Research and Development

Quest to Become a Global Pharma Innovator

We will continue to create innovative drugs, driven by the inquisitive minds of our researchers and a desire to contribute to humanity.

Continuous Creation of Innovative New Drugs

The Daiichi Sankyo Group aims to provide a continuous supply of innovative drugs to patients, and to this end it places emphasis on the research and development (R&D) of first-in-class drugs as a Global Pharma Innovator. The inquiring minds of our researchers and their desire to contribute to the resolution of human health issues are the forces driving us in our R&D efforts.

In the current pharmaceutical market, we cannot expect to achieve sustainable growth with a conventional business model due to various factors such as the decrease of novel compound approvals, increase in biologics, and rise in R&D costs. We therefore need to address unknown biological processes with a flexible mindset and spirit of innovation and ambition to improve productivity by using our experience and creativity. We also need to promote cost reductions to control R&D expenses, which are constantly increasing due to the necessity of conducting large-scale clinical trials, which are often designed to demonstrate efficacy and safety. In order to address these two tasks at the same time, the R&D Unit has defined three principles—leadership, innovation, and efficiency—with the aim of transforming its business model. In addition, “Our Values,” the common standards for value judgments in the Daiichi Sankyo Group, serve as the fundamental and universal foundation for daily activities in the R&D Unit.

Transformation of Mindset for Exercising Leadership

The R&D Unit values leadership and empowerment in its organization and focuses on innovation and taking on new challenges, both of which are aspects of its organizational culture. All employees engaged in R&D are required to be proactive and demonstrate leadership in their field of responsibility, and they are expected to clearly recognize that it is their obligation to accomplish results. Everyone is empowered to play a leading role in their respective area of expertise in order to facilitate swift decision making unhindered by the fear of failure.

Furthermore, the promotion of world-class R&D activities requires bold ideas that break through existing boundaries. That is why we endeavor to strengthen communication between research and development functions across all regions, including Japan, the U.S., Europe, and Asia. We also make efforts to promote cross-cultural understanding with regard to diverse views and backgrounds and to provide a common ground for frank and constructive debate. We hope that collaboration will be born that is unrestricted by functional or local boundaries, and we will work to conceive many creative and groundbreaking ideas.

Initiatives for Realizing Innovation

Innovation created from diversity (Research)

The Daiichi Sankyo Group’s drug discovery efforts span from research to proof of concept (POC).1 The oncology and cardiovascular and metabolic fields have been identified as priority fields for these efforts, and management resources are allocated to these fields in a concentrated manner. Moreover, as a frontier area that spreads across the boundaries of specific disease fields, we are actively engaged in researching new drug functions and treatment methods based on biological mechanisms. The Company is also researching rare diseases and examining drug repositioning2 possibilities. At the same time, Venture Science Laboratories (VSL), an in-house start-up organization, is conducting research related to neurodegenerative diseases.

Furthermore, we are taking advantage of the framework of the Global Health Innovative Technology Fund3 to address issues related to neglected tropical diseases. Research functions related to small molecule medicine are centered in Daiichi Sankyo’s Shingawa and Kasai laboratories. Elsewhere, Plexxikon Inc., in the U.S., is conducting drug discovery in this field using the Scaffold-Based Drug Discovery® platform,4 while Daiichi Sankyo Life Science Research Centre in India (RCI) is researching respiratory and infectious diseases. Each laboratory is advancing new drug research utilizing its individual strengths.

In the field of biologics, Daiichi Sankyo, through its Shingawa R&D Center, Kasai Research and Development Center, and Tatebayashi Plant, is developing technology platforms centered on antibodies and nucleic acids while also advancing biologics-related drug discovery ventures. At the same time, LSI Pharma GmbH, in Germany, is researching antibody agents through collaboration with the Max Planck Institute with the aim of developing oncological treatments.

Drug discovery efforts at ASUBIO PHARMA Co., Ltd., are targeted at the nervous system, the immune system, and regenerative medicine. Meanwhile, Daiichi Sankyo RD Novare Co., Ltd., acts as a pharmaceutical technology platform, while Tissue and Cell Research Center Munich (TCRM), in Germany, advances research utilizing human tissue and cells through joint efforts with a consortium of other organizations.5 Collectively, the entire Group is stepping up personalized medicine6 initiatives. (See chart below.)

1. Identification of predicted features relating to the efficacy and safety of a new drug through clinical trials
2. Discovering new drugs that are effective in treating certain diseases but further developing compounds for which development has been ceased or pharmaceuticals that are effective in treating other diseases
3. An international non-profit organization originating from Japan that promotes new drug discovery
4. A technology asset allowing efficient small molecule designs for virtual drug discovery designs
5. A consortium of academic institutions and private-sector companies that collaborate with the aim of making use of human tissues
6. A medical approach that entails tailoring treatment methods to individual patients based on consideration of their genetic background, physiological conditions, and disease characteristics
Reinforcement of biologics research functions
Biologics are drugs that contain peptides, proteins, nucleic acids, and other biological materials as active ingredients. In addition to growth hormones, insulin, and interferon, which have been sold for more than a decade, many antibody agents have been developed and launched in recent years. In 2014, we pushed forward with the development of technology platforms in this area centered on antibodies and nucleic acids and advanced drug discovery and clinical development initiatives to create new biologics. With regard to antibody agents, we have installed additional production facilities that are compliant with Good Manufacturing Practice requirements, and we are producing investigational drugs. In addition, Daiichi Sankyo has been successful with the in-house development of protein engineering technologies that can be used to design antibodies with superior efficacy that are also incredibly safe, and it has acquired patents for these technologies. Furthermore, the Company is focused on developing antibody-drug conjugates (ADCs), which combine antibody agents and anticancer drugs to realize a powerful tumor-fighting effect. We are developing original technologies related to ADCs and antisense oligonucleotide drugs. After confirming that these drugs possess the superior levels of efficacy and safety expected through non-clinical trials, preparations are under way to quickly bring these drugs to clinical trials. In the field of cancer immunotherapy, which is garnering attention as a viable option for treating cancer, Daiichi Sankyo is engaged in joint research with academic institutions to develop revolutionary and highly specialized technologies. At the same time, we are pushing forward with drug discovery research with the aim of offering new pharmaceuticals based on proteins and peptides to create the next innovation after antibody drugs.

Venture Science Laboratories (VSL)
Established in April 2013, VSL focuses on research targets thought to be related to aging and is undertaking drug discovery ventures aimed at neurodegenerative diseases and a wide range of other ailments. Actively engaged in joint research with the University of California, San Francisco (UCSF), and other globally recognized research institutions, VSL members are working together to achieve high productivity, despite their small team. This commitment has kindled an adventurous spirit in each of VSL’s researchers, and the number of ambitious individuals that seize opportunities in their research attempts is increasing. At the moment, compound screening is under way with regard to various research targets. Although such research is still in the preliminary stages, VSL has already created promising compounds that have the potential of becoming the “seeds” of new drugs.

Promotion of global development
In its development efforts, the Group strives to deliver products created for the global market to medical institutions around the world as quickly as possible. To this end, we are extending our global reach by utilizing our network of bases in Japan, the U.S., Europe, and Asia. Moreover, we have developed a system through which Daiichi Sankyo RD Novare and other Group companies in Japan maintain close coordination with Group companies in the U.S., Europe, and Asia, and development processes are advancing in an integrated manner. Daiichi Sankyo Pharma Development, which has an office in Edison, New Jersey, in the U.S., conducts the management of global clinical trials. Daiichi Sankyo Development Ltd., located in the United Kingdom, is in charge of clinical trials in Europe, whereas clinical trials in Asia are handled by Asian development hubs Daiichi Sankyo Korea Co., Ltd., Daiichi Sankyo Taiwan Ltd., Daiichi Sankyo (China) Holdings Co., Ltd., and Daiichi Sankyo India Pharma Private Ltd. (See chart and “Voice” on page 43.)

Leveraging this development network, we conducted two large-scale phase 3 clinical trials for edoxaban, which were successfully completed thanks to the cooperation of more than 29,200 patients in Japan, the U.S., Europe, and Asia. Edoxaban was launched in Japan and the U.S. in December 2014 and February 2015, respectively, as a treatment for ailments related to venous thromboembolism and non-valvular atrial fibrillation. In Europe, edoxaban received marketing approval by the regulatory authority of Switzerland in March 2015, and then by the European Medicines Agency in June 2015. In the field of pain treatment, one of our areas of specialty, we are advancing the development of mirogabalin, a chronic pain treatment, on a global scale. Phase 3 clinical trials are under way in Japan and Asia to evaluate the drug for the treatment of diabetic peripheral neuropathic pain and postherpetic neuralgia, while phase 3 clinical trials are being conducted in Europe and the U.S. with regard to the treatment of fibromyalgia.

Voice
Effort to address the unique development issues in Asia
The Asia Development Department collaborates with R&D bases in Japan, the United States, and Europe, and structures its operations around two divisions: the Clinical Development Group and the Regulatory Affairs Group. Development-related tasks include confirming the efficacy and safety of drugs through clinical trials. Regulatory affairs duties entail providing data on products to be marketed to the regulatory authorities of each country to obtain approval. Regulatory affairs involve submitting applications for variation or updates of materials related to post-market pharmaceuticals, such as changes in manufacturing locations or package inserts, and obtaining related approval. We are currently preparing to submit an application for marketing approval to the Chinese regulatory authority with regard to edoxaban, a drug that has completed clinical trials and is anticipated to become a flagship product. A culmination of our eight years of seeking out the best practices for operating in the Chinese market, we are compiling the application for this product, which has fulfilled all the requirements expected of applicants undergoing review by the Chinese regulatory authority. Asia differs from Japan, the U.S., and Europe, in that the regulatory conditions differ between countries and regions, forcing us to compile applications to fulfill different requirements for South Korea, Taiwan, Hong Kong, and Southeast Asian countries, for example. This is particularly true in China, where pharmaceutical regulations and other operating conditions are highly volatile. We must conduct business in this country while pursuing constant improvement through a plan-do-check-act (PDCA) cycle implemented based on interactions with the regulatory authorities. We also must carefully explain the special characteristics of the Chinese market to representatives of regulatory affairs and other functions from different regions, as we build upon our experience and share this knowledge through ongoing discussions with these individuals.

One characteristic of the healthcare environment in China is the large number of patients that are broad to community to one country’s large hospitals from remote locations, making it difficult from them to undergo frequent examinations. For this reason, edoxaban, which does not require routine monitoring or dosage adjustments that are necessary when using warfarin, is expected to make significant contributions to healthcare in China. Going forward, we will strive to act as a model for drug development in Asia, carefully accounting for the high number of underweight patients and otherwise adopting a perspective focused on the unique issues faced in this region.

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Daiichi Sankyo Co., Ltd.
The Daiichi Sankyo Group has defined its mission as being “to contribute to the enrichment of quality of life around the world through the creation of innovative pharmaceuticals, and through the provision of pharmaceuticals addressing diverse medical needs.” Fulfilling this mission requires that we draw on the knowledge of numerous researchers. We conduct open innovation activities as one means of tapping such knowledge. This section will explain some of these activities.

Open Innovation

In their R&D activities, pharmaceutical companies must address the recent trend of declining efficiency in the process of discovering new drugs. To remain competitive and continuously create new drugs that are valuable to patients requires a company to be involved with various research themes and take advantage of numerous technology development opportunities to uncover the “seeds” of viable new drugs. In order to accomplish this, it is now absolutely essential for a company to quickly adopt the findings of not only its own R&D activities but also the countless basic research ventures and non-clinical and clinical trials of other companies and subsequently make use of these open innovations. It is becoming more important than ever to utilize the findings of various cutting-edge research projects as well as the technologies born out of these projects.

The discovery and verification of novel pharmaceutical targets as well as other aspects of drug discovery research rely on the results of various basic research projects. At the same time, wide-ranging technology and research platforms are essential to resolving the issues that arise during the R&D process. These platforms are primarily researched at university departments and graduate schools in a wide variety of fields.

The Daiichi Sankyo Group actively promotes open innovation initiatives, as it strives to introduce a diverse range of perspectives into its drug discovery research efforts and merge these perspectives to breed innovation and thereby create revolutionary new drugs.

Comprehensive collaboration with research institutions and collaboration with venture companies

The Group has concluded comprehensive joint research agreements with certain research institutions that boast significant scientific achievements. Through these agreements, we are engaged in closely coordinated industry-academia collaboration. Domestic partners include the National Cancer Center, the National Institute of Advanced Industrial Science and Technology, and the University of Tokyo’s Institute of Medical Science. Research is being conducted on several themes with these partners. Outside of Japan, we have formed comprehensive novel pharmaceutical target discovery research partnerships with institutions including Virtici, LLC and Celldara Medical, LLC of the U.S., Medical Research Council Technology of the United Kingdom, and Lead Discovery Center GmbH of Germany. Joint research projects are being advanced while taking advantage of the networks of these institutions, which have close ties to academia. In addition, Daiichi Sankyo is jointly researching drugs and diagnostic agents for various neurodegenerative diseases together with the UCSF Institute for Neurodegenerative Diseases, in the U.S. We are also conducting comprehensive joint research with Stanford-Burnham Medical Research Institute in the U.S. to study novel drug targets for the treatment of cardiovascular-metabolic diseases.

Networking

Daiichi Sankyo collaborates with participants of business conferences and sections of academic institutions that conduct industry-academia collaboration and actively contacts academic researchers to seek out various opportunities for cooperation. For example, with the aim of effectively utilizing its compound library, Daiichi Sankyo entered into a library-sharing partnership with Astellas Pharma, Inc. in April 2014. Through this partnership, both parties select approximately 400,000 exchangeable compounds from their libraries to share for use by the other party. In addition, we have commenced a joint research project through which a library of compounds designed by Daiichi Sankyo has been supplied to academic institutions so that they may conduct screening.

The Daiichi Sankyo Group’s Open Innovation Model

Expansion of external network for creating new drugs

Securement of various innovation sources

Aiming for various opportunities of open innovation

TaNeDS Collaboration with academic researchers in research areas of interest

Networking
- Project introductions at business conferences
- Networking with technology-licensing organizations/universities
- Connections with academic researchers
- Collaboration related to chemical compound libraries

Funding (OiDE Project)

* Organizations that help transform the successes of university researchers into patented technologies and facilitate the introduction of these technologies at companies

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TaNeDS

Daiichi Sankyo launched its Take a New Challenge for Drug Discovery (TaNeDS) name derived from tane, which means “seeds” in Japanese) collaborative drug discovery project in fiscal 2011. Each year, more than 20 joint research projects are commenced through this program, and by advancing joint research based on selected themes, this program has led to the discovery of several potential candidates for practical application. In fiscal 2013, this program was expanded to the European Union in the form of TaNeDS Global Programme 2014, and a number of projects are under way through this extended program as well.

Funding (OiDE Project)

In September 2013, the Open innovation for the Development of Emerging technologies (OiDE) fund was established through joint investment by Mitsubishi UFJ Capital Co., Ltd., the Organization for Small & Medium Enterprises and Regional Innovation, Japan, and Daiichi Sankyo. Through this fund, we are lending our full support to the development of new drugs and technologies by uncovering promising seeds with the potential to become fundamental pharmaceutical technologies from among the research findings of Japanese universities and other organizations. Venture companies are then founded to develop these seeds.

About the TaNeDS Logo Mark

A symbol of “hope to grow by partnership.” Two people facing each other, holding hands expresses the intention of collaboration, to foster the seeds of hope together.
Global decision making and effective investment of resources

To ensure we are effectively investing in human and material resources, we regularly engage in robust discussions on the productivity of our global research projects from the earliest stages of research based on scientific and business perspectives. Moreover, we pursue ongoing improvements in meeting procedures to expedite decision making, while actively delegating responsibility.

The committees that participate in the Global Executive Meeting of R&D (GEMRAD), at which issues related to the later stages of development are discussed, and the Translational Research-GEMRAD (TR-GEMRAD), at which issues related to the earlier stages of development are addressed, act as the highest decision-making bodies in the Group’s R&D process. Members of these committees include employees of the R&D Unit as well as representatives from a wide range of specialized functions, such as regulatory affairs, product portfolio management, and licensing. These appointments ensure that appropriate decisions are made from a broad perspective. In addition, GEMRAD prioritizes development projects to guarantee that resources are invested effectively and in accordance with portfolio strategies.

Global R&D management

Under the third mid-term business plan, the R&D Unit is tasked with meeting three numerical goals each year. These goals are (i) to launch two new products for major indications, (ii) to advance four projects into late-phase clinical development after POC, and (iii) to advance nine projects into phase 1 clinical studies. In fiscal 2014, the first goal was met by launching edoxaban in Japan and the U.S. as well as pranaromide in Japan. We are fully aware that our research is strongly required with regard to human research subjects and laboratory animals. We are aware that our research is strongly required with regard to human research subjects and laboratory animals. In fiscal 2014, the first goal was met by launching edoxaban in Japan and the U.S. as well as pranaromide in Japan. We are fully aware that our research is strongly required with regard to human research subjects and laboratory animals.

Daiichi Sankyo has established the Detailed Rules on Animal Experimentation based on Japanese laws and guidelines, including the Act on Welfare and Management of Animals and Fundamental Guidelines issued by the Ministry of Health, Labour and Welfare regarding how institutions under its jurisdiction conduct animal experiments and related activities. In acting in accordance with these rules, we practice the 3Rs of animal research.*2 All animal-use protocols must be approved by the Company’s Institutional Animal Care and Use Committee, and only the protocols that have received approval can be made. Moreover, researchers conducting animal research are required to receive specialized training each year. To confirm that our experiments are in compliance with Japanese laws and guidelines, we conduct animal self-inspections and also seek accreditation from external organizations. In fiscal 2014, the Kasai R&D Center renewed its certification from the Japan Health Sciences Foundation’s Center for Accreditation of Laboratory Animal Care and Use. At the same time, the Shิงawa R&D Center received accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). (See “Voice” on page 47.)

Measures to deal with biohazards

The Company practices strict compliance with the Act on Prevention of Infectious Diseases and Medical Care for Patients Suffering from Infectious Diseases and the Act on Domestic Animal Infectious Diseases Control. An internal biohazard committee has been established that includes rules for the safe handling of pathogens and pathogen-containing materials. The Biosafety Committee fulfills the role of determining proper operating rules. In addition, we have formulated internal rules for recombinant DNA experiments to ensure that genetically modified organisms are managed appropriately in accordance with the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Act on Biosafety). Furthermore, the Recombinant DNA Safety Committees checks all research protocol to ensure compliance with the Cartagena Act on Biosafety prior to commencement. To prevent accidents that may occur during recombinant DNA experiments, the Committee takes steps to identify all possible risks related to accidents by researchers and formulate countermeasures to address these risks. Training is also provided to recombinant DNA researchers to help prevent accidents.

Fair utilization of genetic resources

Concerning the preservation of biodiversity, sustainable use, and fair and equitable sharing of the benefits arising out of the utilization of genetic resources, we abide by the Convention on Biological Diversity and the Bonn Guidelines. Moreover, we are giving full consideration to recent domestic developments related to the Nagoya Protocol, which was adopted during the 10th Meeting of the Conference of the Parties to the Convention on Biological Diversity (COP 10).

R&D Ethics

Maintaining social trust is crucial to a company’s business activities. At the same time, it is vital to remain constantly aware of the importance of compliance. In life science-oriented industries, in particular, higher ethical standards are required with regard to human research subjects and laboratory animals. We are aware that our research is strongly related to the health and safety of people, and therefore we emphasize values based on bioethics.
A variety of intellectual properties are used throughout the process of bringing drugs from the R&D phase to operations on a global scale, we are expanding the range of countries in which we acquire intellectual property.

Areas in which intellectual property rights must be considered while protecting its own intellectual property rights in a variety of areas and respecting those of other companies include biologics, generic products, biosimilars, vaccines, and over-the-counter (OTC) drugs. As we develop our operations on a global scale, we are expanding the range of countries in which we acquire intellectual property. In addition, intellectual property representatives have been positioned in Japan, the U.S., Europe, and India to ensure timely and accurate responses to the Company’s intellectual property needs that are fine-tuned to the respective region. We are also building cooperative relationships with external partners that possess cutting-edge scientific and technological capabilities to guarantee we are able to continue creating innovative new drugs through the utilization of open innovations and open development projects.

Protection of Intellectual Property

Line-ups of Products Responding to Medical Needs

The Daiichi Sankyo Group’s product portfolio includes drugs for the treatment of hypertension, infectious diseases, dyslipidemia, and other conditions. We aim to develop a line-up of products for disease areas where unmet medical needs are great. To this end, we are advancing late-stage R&D projects in the oncology and cardiovascular and metabolic fields, while at the same time developing pain relief drugs with the aim of providing additional treatment options. The following are major pharmaceuticals that are in the late stages of development.

Quizaritinib (AC220)

Quizaritinib is a FLT3-ITD (fms-like tyrosine kinase 3 internal tandem duplication) inhibitor for which the Company received development rights for through the acquisition of bio-field venture company Ambit Biosciences Corporation. We are conducting phase 3 clinical trials for quizaritinib as a treatment for acute myelocytic leukemia in Europe and the U.S.

Pexidartinib (PLX3397)
Pexidartinib is a kinase inhibitor developed by Group company Flexenon Inc. After generating impressive results in a phase 1 clinical trial for the treatment of pigmented villonodular synovitis, a type of giant cell tumor of the tendon sheath, Pexidartinib was approved as an orphan drug*1 by the U.S. Food and Drug Administration. We are currently advancing phase 3 clinical trials to test this drug as a treatment for giant cell tumors of the tendon sheath in Europe and the U.S.

Mirogabalin (DS-5565)

Mirogabalin is a chronic pain treatment developed by Daiichi Sankyo that controls the excessive excretion of neurotransmitters in nerve endings to relieve associated pain. Two phase 3 clinical trials are under way in Japan and Asia to evaluate the drug for the treatment of diabetic peripheral neuropathic pain and postherpetic neuralgia. In addition, phase 3 clinical trials are being conducted in Europe and the U.S. with regard to the treatment of fibromyalgia.

Hydromorphone (DS-7113)

Hydromorphone is a narcotic analgesic marketed for more than 80 years outside Japan that has been positioned as a standard drug for pain control in the World Health Organization’s guidelines for the treatment of cancer pain. However, this drug has not been approved in Japan. Therefore, this drug has been designated as an unapproved drug by an evaluation committee on unapproved and off-label drugs with high medical needs of the Ministry of Health, Labour and Welfare. Daiichi Sankyo is advancing the development of this drug, as this task is viewed as a social responsibility.

CHS-0214

CHS-0214 is a biosimilar (biogenics) of etanercept, a treatment for rheumatoid arthritis and other autoimmune diseases. Daiichi Sankyo has concluded an agreement with Coherus BioSciences, Inc., of the U.S., regarding strategic collaboration for commercializing biosimilars in Japan. CHS-0214 is currently being tested as a treatment for rheumatoid arthritis in a phase 3 clinical trial in Japan.

CL-108

CL-108 is a novel hydrocode combination product containing hydrocode, acetaminophen, and promethazine. The Company has entered into a strategic collaboration agreement with Charleston Laboratories, Inc., regarding the future development of CL-108 as well as its commercialization in the U.S. We are currently advancing a phase 3 clinical trial in the U.S. to test this drug for the treatment of acute pain as well as the reduction of opioid-induced nausea and vomiting.

VN-100

VN-100 consists of an intradermal injection syringe for influenza that is prefilled with HA vaccine. It was developed jointly by Terumo Corporation, Japan Vaccine Co., Ltd., Kissei Pharmaceutical Co., Ltd., and Daiichi Sankyo based on an agreement concluded with Terumo February 23, 2012, regarding the practical application of its intradermal infectious disease vaccines. The syringe is specially designed to prevent the leakage of vaccines to the peripheral arteries and nerves, and it is therefore anticipated to help eliminate the burden placed on recipients of vaccinations, including the mental burden from fear of needles. Domestic manufacturing and marketing approval was received for this product in April 2015.

For more information, please refer to “Major R&D Projects” on page 15.

Collaboration with External Partners

Daiichi Sankyo is actively collaborating with external partners to swiftly provide patients with continuous supply of new drugs. Such collaboration includes licensing activities, which entail incorporating the R&D successes of bio-field venture companies and other external organizations into the Company, and activities for developing our own compounds together with partners that possess superior know-how.

Co-commercialization agreement for opioid-induced constipation treatment MOVANTIK™ between AstraZeneca and U.S. subsidiary

In March 2015, U.S. subsidiary Daiichi Sankyo Inc. (DSI), concluded an agreement with Astra Zeneca plc through which the companies will conduct co-commercialization in the United States for MOVANTIK™, a treatment for constipation induced by opioids (narcotic analgesics).

Daiichi Sankyo has been participating in sales promotions since May. Under the agreement, AstraZeneca will be responsible for manufacturing, and sales of MOVANTIK™ will be recorded by this company, which in turn will make sales-related commission payments to DSI.

Partnership between UCB and Daiichi Sankyo to co-commercialize epilepsy treatment lacosamide in Japan

In November 2014, Daiichi Sankyo concluded an agreement with UCB Biopharma SPRL for the co-commercialization of this company’s lacosamide epilepsy treatment in Japan. UCB applied for approval for lacosamide in Japan in 2015. In supplying lacosamide to the Japanese market, UCB will be responsible for manufacturing, while the Company will handle sales and distribution.

In-licensing agreement for hydrocode combination product CL-108 from U.S.-based Charleston Laboratories

In August 2014, the Company concluded an in-licensing agreement with Charleston Laboratories, Inc., for CL-108, a novel hydrocode combination product. This drug will further strengthen Daiichi Sankyo’s pain-relief product portfolio, which includes such noteworthy products as Mirogabalin and MOVANTIK™.

Acquisition of U.S. Ambit Biosciences Corporation

In November 2014, the Company acquired Ambit Biosciences Corporation, of the U.S. Daiichi Sankyo has defined the medium-to-long-term goal of continually providing groundbreaking new drugs in the oncology field, and this acquisition is expected to help further strengthen the Company’s oncology product portfolio.

Development of nucleic acid treatment for Duchenne muscular dystrophy through joint investment with Innovation Network Cooperation of Japan

In March 2013, the Company established Orphan Disease Treatment Institute Co., Ltd., with Innovation Network Cooperation, of Japan, and other organizations. We are currently co-developing with Orphan Disease Treatment Institute a nucleic acid treatment drug for Duchenne muscular dystrophy (DMD). This drug functions during the process of synthesizing a protein from a dystrophin gene by skipping the splicing of the premature m-RNA exons 45 to create a mature m-RNA of dystrophin protein that is incomplete but functional. During fiscal 2015, we plan to commence a clinical trial of the drug on a part of DMD patients for whom it is anticipated to prove effective.
Pharmaceutical Technology

Quest to Become Daiichi Sankyo as a Global Pharma Innovator
We will develop candidate compounds into commercially viable pharmaceutical products.

Creation of High-Value-Added Products Using Pharmaceutical Technology

Efficacy and safety are the primary requirements for any pharmaceutical product. However, it is becoming significantly more important to provide pharmaceutical products that can be more easily used by patients, healthcare professionals, and caregivers in order to respond to the rapid aging of society and the needs for advanced medical care. Examples of user-friendly pharmaceutical products include extended-release tablets, which reduce the frequency at which pharmaceuticals must be administered, and orally disintegrating (OD) tablets, which can be taken without water. Meanwhile, examples of innovation for healthcare professionals include syringes that are prefilled with drug solutions to reduce the hassle of preparation and the risk of needle injuries, as well as IC tags for pharmaceutical products or packages that are helpful in preventing medical errors. Additionally, we are utilizing various formulation technologies to provide user-friendly pharmaceutical products adding new value. Such innovations on this front include package designs and tablets with the product name printed on them in order to prevent any misuse. (See “Voice” on page 51.)

We are advancing the development of new synthetic processes based on the eco-friendly concept of “green chemistry,” which is aimed at achieving global environmental sustainability through means such as preventing pollution and reducing consumption of materials and energy. Such new pharmaceutical technologies have been optimally applied to the following products that are currently offered: Olmetec, Rezaltas combination tablets, Memary, Inzor, Omnieaque, PRAHIA, Elrient (Japan), and LIXIANA.

Pharmaceutical Technology

Pharmaceutical technology is a collective term for technologies to develop candidate compounds that have either been discovered or created into commercial pharmaceutical products. These products are made by transforming chemical compounds with useful effects on the human body into high-quality dosage forms that can appropriately exhibit effects against disease. Pharmaceutical technologies are divided into the following three functions. (See chart below.)

• Process technology for researching synthetic methods to be used to manufacture candidate compounds efficiently and consistently in large amounts and with high quality
• Formulation technology for investigating dosage forms, formulations, and packages based on absorption stability, and usability in consideration of the characteristics of candidate compounds, and then selecting and preparing the optimal administration form
• Analytical and quality evaluation technology for establishing a variety of analysis and quality evaluation systems to properly and appropriately assure the quality of the pharmaceutical products

In July 2015, we began selling Memary OD tablets with the name printed on each pill to clarify that these are the improved OD tablets. Others even stated that patients, who previously refused their pills, sometimes had stopped refusing after switching to OD tablets. Others even noted that patients who previously refused their pills, sometimes going as far as spitting them out, now take their medicine without any problems, which has greatly reduced the amount of time they spend administering pharmaceuticals.

Voice

Development of designs based on the user’s perspective

I am in charge of developing tablets, capsules, and other orally administered solid formulations. At Daiichi Sankyo, we are committed to developing pharmaceuticals that are easy to take for patients and easy to administer for individuals assisting in their care. Memary OD tablets were our first OD formulation. In developing the tablets, our main focus was enabling two opposing characteristics. The tablet had to be soft enough to ensure that it could dissolve quickly in a patient’s mouth. At the same time, it needed to be hard enough to be easily handled by patients, pharmacists, and caregivers and prevent breaking should the tablets be dropped. We developed the formulation of the OD tablets through a trial and error process that entailed examining and evaluating formulations and utilizing numerous manufacturing processes and raw materials. Furthermore, taste is more of a concern with OD tablets than with conventional tablets, so it was also important to control the bitterness of the medicine to provide a taste that would make ingesting these tablets easier for patients. Due to these efforts, Memary OD tablets have received much praise from patients, pharmacists, and caregivers alike. Many have mentioned that the change to the OD tablet made taking the medicine easier or that patients who were previously unwilling to take their pills had stopped refusing after switching to OD tablets. Others even stated that patients, who previously refused their pills, sometimes going as far as spitting them out, now take their medicine without any problems, which has greatly reduced the amount of time they spend administering pharmaceuticals.

Major Initiatives

Creation of high-quality products using advanced technologies

We are actively creating product quality designs based on the new Quality by Design (QbD) framework for quality assurance. For example, by applying advanced QbD approaches, LIXIANA, oral anticoagulant tablets, became the first pharmaceutical in Japan to utilize the real-time release testing (RRT) for all release tests.

Generally, the quality of pharmaceuticals is tested after production—products that have been assured to be up to quality are subsequently released. In contrast, RRT is a sophisticated quality assurance system that utilizes advanced analytical technologies to manage quality during production and thereby eliminates the need for post-production quality tests. We are earnestly committed to ensuring quality by continuing to apply advanced technologies to our products.

Social issues related to pharmaceutical technologies

Recently in Japan, the aging of society has driven an increase in the number of people requiring long-term care, and these individuals are often prescribed a wide variety of pharmaceuticals to treat their illnesses. It is common for such individuals to forget to take or mistakenly administer their medicine—or fail to use medicine altogether—due to an inability to open the packaging. These factors can decrease the level of medical compliance and adherence practiced by such individuals, hindering the effectiveness of their treatment, and such trends are becoming a social issue. At Daiichi Sankyo, we are advancing research and development to create high-value-added products that help address this issue by responding to the needs of patients, caregivers, and healthcare professionals.
Prioritizing Usability

Memary OD tablets

One high-value-added product development by the Company is Memary OD tablets, which were launched in May 2014. This drug was developed with the aim of limiting the advancement of dementia in patients with moderate-to-severe Alzheimer’s disease. It is difficult for dementia sufferers to manage their own schedules for taking medicine, and common for them to refuse to use prescribed pharmaceuticals. Accordingly, the task of managing administration often falls upon the caregivers of such patients. We therefore believe that it is possible to decrease the burden on caregivers by providing OD tablets for dementia patients that also have difficulty consuming food or water. Memary OD tablets were developed using Daiichi Sankyo’s OD tablets platform technology and are manufactured to be dissolved with saliva or small amounts of water. This means the patients experiencing difficulty swallowing pills or facing limitations on fluid intake can still take these tablets easily. In addition, we took steps to reduce the bitterness of these tablets, which we expect will prevent patients from spitting them out and thereby contribute to improved medical adherence. Furthermore, each tablet is printed with the name “Memary OD” as well as the dosage in clear lettering (see photographs below). Such labeling makes it easy to recognize these tablets and determine dosages, thereby aiding caregivers in accurately administering this product. Moreover, this information is printed on both sides of tablets, allowing for easy discernment even when the tablets are contained within blister package sheets.

These features make Memary OD tablets an easy-to-use, easy-to-recognize, and high-value-added product prioritizing usability.

<table>
<thead>
<tr>
<th>5 mg tablet</th>
<th>10 mg tablet</th>
<th>20 mg tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>High clarity (600 dots per inch)</td>
<td>Printed tablets in blister package sheets</td>
<td></td>
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</tbody>
</table>

HANP Injection 1000

HANP Injection 1000 is a freeze-dried pharmaceutical used to treat acute heart failure. Originally launched in 1995, this product initially had to be stored at below 10°C. Aiming to enhance usability, we changed the formulation for this product and were eventually successful in developing a formulation with improved stability. Furthermore, the product quality design for HANP Injection 1000 was reconstructed based on the QbD framework, enabling us to establish manufacturing conditions that optimized freeze-drying requirements through skillful innovation. We were thereby able to create an enhanced form of HANP Injection 1000, which is a new formulation that features the same quality as before while allowing for storage at room temperature, making it significantly more convenient to use.

After the Great East Japan Earthquake devastated many facilities and created electricity supply constraints, Japan was faced with a situation in which pharmaceuticals could not easily be stored at refrigerated temperatures. As such, the medical community was quite pleased to hear that HANP Injection 1000, a drug necessary for treating the serious condition of heart failure, could now be stored at room temperature. Going forward, we will continue to utilize our formulation technology to enhance the value of products throughout the entirety of their long life cycle.

External Voice

Contributions to the medical field made by accurately transmitting feedback from healthcare professionals and patients to pharmaceutical companies

I am a marketing specialist at the Alfresa Group, Japan’s largest pharmaceutical wholesaler. My duties are diverse, primarily involving the conduct of business discussions as part of marketing activities. In the course of these activities, I quickly and accurately communicate product information to the medical front. Moreover, I visit hospitals and clinics nearly every day to have in-depth conversations with doctors and pharmacists to solicit opinions and guidance. I work in Kakogawa City, Hyogo Prefecture, which is home to around 70 hospitals and clinics and 30 insurance pharmacies. At the same time, I am responsible for roughly 230 pharmaceutical companies, making for a busy but rewarding job.

One step past doctors and pharmacists brings us to the patients who take pharmaceuticals on a daily basis. The opinions of patients are indispensable to the improvement of formulations. Therefore, I strive to accurately transmit this feedback to pharmaceutical companies so that it may be reflected in efforts to improve upon formulations. In the past, comments from insurance pharmacies that blister package sheets were too big and would not fit in shelves have led to changes in the size of sheets. Likewise, the opinion that certain tablets were bitter and hard to swallow has resulted in pharmaceutical companies switching to OD tablets. Moreover, after it was brought to our attention that the packages and blister package sheets of some products looked too similar to those of others, we changed packaging designs to prevent dispensing errors.
Transformation of the Supply Chain in Response to Changing Times

The operating environment for the pharmaceutical industry is changing rapidly as the pharmaceutical market grows on a global basis, pharmaceutical needs diversify, and generic drugs quickly permeate the domestic market. Moreover, these changes are making our supply chain increasingly more complex. In today’s market, it is important that companies practice good corporate social responsibility and optimize a global product supply chain. In order to ensure high quality, steady and uninterrupted drug supply, and low costs, we strive to practice seamless business operations without any barriers. The flow of information that could create misunderstanding between different parts of the organization is critical. In the highly volatile era, it is important to create strengths by aligning the entire organization with the same thoughts. We will continue to foster a corporate culture that promotes the refinement and integration of all supply chain technologies, which are to be backed by employees’ knowledge and experience, to guarantee that our performance is always the best. (See “Voice” on page 55.)

Major Initiatives

We will leverage our advanced technological capabilities to efficiently produce consistently high quality drugs and to provide a steady supply of these drugs to patients around the world.

Reorganization of Japan’s supply chain functions

Effective April 1, 2015, the previous three domestic supply chain-related subsidiaries were reorganized into two companies, one for manufacturing APIs and the other for manufacturing pharmaceuticals and conducting logistics. In addition, new investigational drug manufacturing functions have been installed in the Supply Chain Unit. We have thereby constructed a supply chain for new investigational drugs that can also provide these products at any stage of operations, ranging from development to commercial use. Furthermore, we are working to improve the efficiency of the foundations of our business operations. For example, we are establishing frameworks to allow technologies to be transferred with minimal hassle between divisions, to ensure the manufacturing processes and analytical technologies developed during the period of new investigational drugs can be applied to the commercial production phase.

Recognition of and Response to Social Issues in the Supply Chain

Supply chain technologies also include management practices, such as those for cutting costs through collaboration with our business partners and for developing flexible production plans. Furthermore, in order to ensure high quality, steady and uninterrupted drug supply, and low costs, we strive to practice seamless business operations without any barriers. The flow of information that could create misunderstanding between different parts of the organization is critical. In the highly volatile era, it is important to create strengths by aligning the entire organization with the same thoughts. We will continue to foster a corporate culture that promotes the refinement and integration of all supply chain technologies, which are to be backed by employees’ knowledge and experience, to guarantee that our performance is always the best. (See “Voice” on page 55.)

As our entire business expands globally, we are establishing and optimizing a global product supply chain that is suited to the lifecycles of individual products by fully leveraging the strengths of all manufacturing sites. In advancing these initiatives, the Daiichi Sankyo Group has received marketing approval for edoxaban in Japan, the U.S., and Europe, and we plan to expand the range of regions in which this drug is sold to include the Asia, South & Central America region.

One social issue needing to be addressed in the supply chain is the increased social demand for measures to assure the reliability of pharmaceuticals. Traditionally, pharmaceutical quality assurance efforts have been primarily focused on the manufacturing process, where we have ensured reliability by conducting Good Manufacturing Practices (GMP) for pharmaceutical and peripheral manufacturing and quality management. In recent years, pharmaceutical companies have also stringently ensured reliability with regard to the storage and transportation of pharmaceuticals and have conformed to Good Distribution Practices (GDP). Daiichi Sankyo has developed its own GDP guidelines, which are implemented while utilizing serialization*1 measures in Japan and other regions for certain products as well as various packaging and labeling.

Promotion of socially responsible procurement

To further promote socially responsible procurement practices, the Supply Chain Unit periodically assesses suppliers of raw materials in Japan to evaluate their ability to ensure quality and provide a stable supply of the desired resources. In addition, in fiscal 2014, we held meetings with major suppliers that had initiated CSR self-evaluations*2 with the aim of improving socially responsible procurement measures. These suppliers scored higher on re-evaluations, and these evaluations can thus be seen as a successful example of our initiatives to work together with partners (suppliers) by practicing socially responsible procurement activities. Going forward, we will promote socially responsible procurement as one facet of our corporate activities, which emphasize sustainability in addition to superior quality, steady drug supply, and low costs.

Steady Supply of Edoxaban

We have received marketing approval for edoxaban in Japan, the U.S., and Europe, and we plan to expand the range of regions in which this drug is sold to include the Asia, South & Central America region.

*1. Tracking method employing serial numbers to help prevent the spread of counterfeit pharmaceuticals.
*2. Self-evaluations utilizing check sheets that include items related to human rights, labor conditions, corporate ethics, environmental measures, reliability of supply capacity, and information security.
Quality and Safety Management

Quest to Become a Global Pharma Innovator

We will secure quality and safety to deliver reliable drugs.

Quality and Safety Management Unit

The success of Daiichi Sankyo’s investigational and marketed drug products depends on quality manufacturing as well as appropriate data management. The Daiichi Sankyo Group’s Quality and Safety Management Unit was developed to help deliver reliable drugs to patients and healthcare professionals all over the world. This unit focuses on the following four functions, the last of which was introduced in April 2015.

1. Quality assurance of a steady supply of drugs (products) to the world through manufacturing and analytical information reviews related to areas ranging from clinical trials to post-marketing

2. Assurance of patient safety through safety measures based on analyses and evaluations of information on adverse drug reactions received from all stages of use ranging from clinical trials to post-marketing

3. Quality assurance of data (efficacy and safety information) in areas ranging from R&D to post-marketing to validate the accuracy of the information we provide about the effects of our products on patients

4. Information creation and value improvement for drugs through clinical studies and post-marketing studies based on various needs of healthcare professionals for marketed products

These four functions support the value chains of R&D, pharmaceutical technologies, supply chains, and marketing and sales, which are major areas of activity for a pharmaceutical company.

Social Expectations Related to Quality and Safety Management

In recent years, countries around the world have been instituting increasingly rigorous standards for the quality and safety of pharmaceuticals. In regard to quality, manufacturing and quality management procedures are expected to be at the levels stipulated by international standards. Representative examples of such standards include the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) and Good Manufacturing Practices (GMP) for pharmaceutical manufacturing and quality management. There is also a growing expectation that companies conform to Good Distribution Practices (GDP) for pharmaceuticals. In regard to safety, companies are expected to globally manage safety information in accordance with the regulations of relevant countries. For example, in Japan, pharmaceutical companies must provide a sufficient amount of information on their drugs from the perspectives of both healthcare professionals and patients to facilitate proper use.

The Quality and Safety Management Unit is proactive in ensuring compliance with these expectations. To uphold quality standards, the unit works in close coordination with the Supply Chain Unit to encourage subcontractors to observe the PIC/S, GMP, and GDP in their activities.

In regard to safety, our main businesses in Japan, the U.S. and Europe as well as other important business units have introduced the Integrated Pharmacovigilance Operations System (IPOS) global safety database to realize more sophisticated management of safety information. In addition, in Japan the Company has formulated and disclosed pharmaceutical risk management plans (RMPs) to promote sophisticated management of safety information. In addition, safety information reviews related to areas ranging from clinical trials to the world through manufacturing and analytical information reviews related to areas ranging from clinical trials to post-marketing.

Major Initiatives

Promotion of proper drug use

Two years have passed since Japan instituted regulations requiring pharmaceutical companies to develop RMPs. Daiichi Sankyo, therefore, has released RMPs for prasugrel, denosumab, and edoxaban, and the Company is pushing forward with other safety measures. RMPs play an important role in fostering a shared understanding among healthcare professionals, government authorities, and pharmaceutical companies with regard to the risk management measures necessary for specific marketed pharmaceuticals. Moreover, we recognize that by utilizing RMPs to enhance safety measures for the pharmaceuticals we market, we are able to help patients and their families live healthier lives. (See “Voice” on the right-hand side of this page.)

Initiatives related to edoxaban

Currently, edoxaban has been approved for three indications in Japan. The administration methods and dosage amounts vary for each disease. In addition, edoxaban’s flexible dosing strategy offers physicians the advantage of dose reduction for important patient factors that are known to increase bleeding risk such as advanced age, low body weight, and reduced renal function. We have thus taken steps to make proper usage information easier to understand to clarify usage procedures. Specifically, we have developed separate documents for each disease, and extra attention has been paid to package inserts for customers, such as using different-colored covers and photographs to more easily distinguish which document is needed.

Improvement of pharmacovigilance and quality assurance levels in the ASCA region

The pharmaceutical markets in the Asia, South & Central America (ASCA) region are growing rapidly, and to continue expanding our operations in these markets, complying with laws and regulations of the different countries in this region is of paramount importance. Sharing information among operations is crucial in other countries and regions in which we market the same drugs, such as Japan, the U.S., and Europe. Therefore, it is essential we continue to develop pharmacovigilance* and quality assurance levels at our units in the ASCA region.

The Quality and Safety Management Unit is providing support and guidance to Group companies in these regions to help facilitate the sharing of information on a global scale to improve pharmacovigilance and quality assurance levels. Specific areas of attention include (1) activities related to the enhancement of quality assurance systems at production bases in these regions, (2) the development of contracts with licensees to ensure the exchange of safety information, and (3) measures to ensure the reliability of approval application materials for edoxaban and respond to related inspections.

Creation of pharmaceutical information

The Quality and Safety Management Unit is responsible for developing internal inspection systems for ensuring the utmost levels of ethics and transparency. The unit is aggressively conducting clinical studies with the aim of creating information with substantial medical and scientific merits. For example, the unit investigated treatment conditions with regard to edoxaban to aid in formulating life-cycle management strategies for this drug. It also conducted clinical studies in relation to prasugrel to ensure its competitiveness over rival products. The findings of such investigations are incorporated into theses and actively presented at academic events.

* To collect, evaluate, and analyse adverse events of drugs (including investigational products) or other drug-related matters and implement initiatives for their prevention

Voice

Creation of proper-usage documents enables Daiichi Sankyo to remain a leading company in terms of providing safety information.

Daiichi Sankyo’s expertise in creating package inserts, interview forms, RMP materials, and other proper-usage documents is consolidated within the Safety Information Management Group, which was established in April 2015 with the aim of strengthening information provision capabilities. Stabilized in this division, I am responsible for constructing and managing package inserts and for formulating and editing the proper-usage documents that provide healthcare professionals and patients with information on the adverse drug reaction and proper-usage methods in Japan. These documents have a tendency to be very long and repetitive. For this reason, I take special care to make documents as simple and easy to read as possible to help their busy readers better utilize them for their desired results. I carefully draft and edit these documents to present them in a clear and reader-friendly manner.

For example, when I created a document for edoxaban, I continued to engage in rigorous discussions with related divisions in house, head doctors, and representatives from the Pharmaceuticals and Medical Devices Agency throughout the process. In order to accommodate for differing needs of various users, I conducted a proper-usage guide for edoxaban for use by healthcare professionals and a separate booklet aimed at patients.

At Daiichi Sankyo, we are committed to providing high-quality products to patients by maximizing the efficacy of pharmaceuticals while minimizing their risks. As I contribute to this endeavor, I am always growing more aware of the importance of reviewing products from the perspective of adverse drug reaction as well as efficacy, and of supplying timely information. I will continue to devote my efforts to helping Daiichi Sankyo provide appropriate safety information on its pharmaceuticals.
Since fiscal 2010, Daiichi Sankyo has launched a number of new products. These new products include Rezaltas, an antihypertensive agent; Memary, a treatment for Alzheimer’s disease; NEXUM, a treatment for ulcer; RANMARK, a treatment for bone complications; and PRALIA, a treatment for diabetes. Daiichi Sankyo’s education and training program for newly employed MRs has a strong reputation for its constant state of change that corresponds to the diversification of medical needs. To continue to be recognized as a trusted partner by healthcare professionals and to be recognized for its medical and therapeutic fields, Daiichi Sankyo’s business is the Company continually releases new products in the cardiovascular field, which has been identified as a priority field.

Thrombosis drugs marketed in Japan include the recently launched Elniten, an antplatelet agent with the potential to become the standard treatment in Japan for thrombosis and embolism, as well as LIGIKAN, an oral anticoagulant originally marketed for prevention of VTE post-major orthopedic surgery since 2011, and for which new indications in atrial fibrillation and VTE were recently acquired. In regard to diabetes drugs, in addition to marketing TENELIA, a DPP-4 inhibitor manufactured by Mitsubishi Tanabe Pharma Corporation, we are participating in joint-promotion campaigns with this company for canagliflozin, a GLP-1 receptor agonist manufactured by Takeda Pharmaceutical Industries Limited, and for the treatment and prevention of VTE were recently acquired. In regard to diabetes drugs, in addition to marketing TENELIA, a DPP-4 inhibitor manufactured by Daiichi Sankyo, we are participating in joint-promotion campaigns with this company for canagliflozin, a GLP-1 receptor agonist manufactured by Takeda Pharmaceutical Industries Limited, and for the treatment and prevention of VTE.

Going forward, we will nurture these new products into core earnings pillars and achieve sustainable growth by leveraging our extensive product portfolio. At the same time, we will foster collaboration among Group companies.

Voice

My experience undergoing training to study for the MR certificate test

I joined Daiichi Sankyo in 2014 and I am now working in the Kawasaki Sales Office of the Saitama Branch, where I work with physicians in private practices. Aiming to become a reliable MR, I spent five months following my entry into the Company at a training facility. There, together with 44 of my peers, I took part in an intensive training program designed to help us acquire the MR certificate, a standard industry qualification. Throughout the training period, we always acted in teams of five. Each team included people with different educational backgrounds, such as those who had studied pharmacy, medical science, or liberal arts in college. As I had studied liberal arts, I had only a very small amount of basic medical and pharmaceutical knowledge, and this team structure proved highly informative for me. Furthermore, we were taught to take numerous fasts during the period, for which total team scores were ranked. Motivated to compete with other teams, this system encouraged us to support each other and work together to improve each of our performances. It also allowed us to share a feeling of accomplishment when we succeeded. More importantly, this experience instilled in us a spirit of teamwork, which is a core element of Daiichi Sankyo’s corporate culture. I was assigned to my work post in August 2014. Over the period leading up to the MR certificate test in December, I continued to study on my own while also performing other duties. I believe that this system and the corporate culture surrounding it is the secret behind Daiichi Sankyo’s ability to have 100% of its MRs pass the MR certificate test for five straight years. After having the experience of saving hospitals and other market segments, I eventually hope to be placed in charge of training the next generation of new employees.

Hiroki Shiota
Kawasaki Sales Office
Area Sales Promotion Department
Saitama Branch
In fiscal 2014, downward pressure was placed on the earnings of Daiichi Sankiyo, Inc. (DSI), by intensified competition following the release of a generic rival for the olmesartan franchise. With regard to Welchol, a treatment for hypercholesterolemia and type 2 diabetes mellitus, competing generic drugs were not released during fiscal 2014, contrary to expectations. As a result, both Welchol and Effient experienced sales that were in line with the previous fiscal year. In addition, edoxaban was launched in the North American market under the brand name Savaysa in February 2015. DSI’s revenue amounted to ¥173.0 billion in fiscal 2014, down 0.7% year on year. In fiscal 2015, we will continue to implement marketing initiatives aimed at patients, healthcare professionals, and other stakeholders with regard to DSI’s mainstay olmesartan franchise, even in the midst of the fierce competition from generic drugs in the antihypertension treatment market. Our sales forecasts for fiscal 2015 are based on the assumption that a generic drug will be released to compete with Welchol. With regard to the newly launched Savaysa, we plan to construct sales strategies and steadily implement marketing and contracting strategies, while taking into account labeling restrictions, in order to expand sales and grow this drug into a mainstay product. Also, DSI concluded a co-commercialization agreement with Astrazeneca plc in March 2015 for MOVANTIK, a treatment for constipation induced by opioids. DSI will quickly develop sales promotion strategies for this drug through collaboration with Astrazeneca.

Luitpol Pharmaceuticals, Inc. (LPI), which specializes in anemia treatments and injection treatments, recorded revenue of ¥77.4 billion, up 44.8% year on year. This impressive increase in sales can be attributed in part to the stable earnings base formed by Vencofen, an iron-deficiency anemia treatment for patients with chronic kidney disease, as well as the launch of the new anemia treatment, LIXIANA, in fiscal 2013, which has served as a major driving force behind sales of this company’s entire iron supplement franchise. In addition, LPI launched levofloxacin. We will focus on improving manufacturing processes with the aim of ensuring a stable supply of quality products to the market.

In fiscal 2014, revenue for Daiichi Sankyo Europe GmbH (DSE) was down 0.6% year on year, to ¥383.5 billion. This outcome was due in part to the benefits of yen depreciation, which compensated for the large decrease in the government-defined selling price for mainstay product olmesartan in Germany.

The European Medicines Agency approved edoxaban in the European Union under the brand name LIXIANA in June 2015. DSE is in the process of launching LIXIANA in the EU, and this product is expected to make favorable contributions to performance going forward. As a part of launching this major product, the company is working to restructure its sales systems to shift from its current “Share of Voice” model to an “Access” model. This transition will entail revising current sales strategies to emphasize the volume of information provided to healthcare practitioners. Through these new strategies, large quantities of high-quality information will quickly be provided to various stakeholders in accordance with their specific needs, which vary based on their country or region or with which of the processes leading up to prescription decisions they are associated. As another part of this reorientation, DSE is cutting back on staff numbers and thoroughly strengthening core functions.

Through this “Access” model, DSE will further build upon the sales capabilities developed through its olmesartan franchise to maintain the strong presence of existing products in Europe while maximizing the benefits from the new introduction of LIXIANA.

In fiscal 2014, we implemented initiatives to maximize sales of olmesartan, levofloxacin, and other existing products, and to rapidly develop and launch new products, such as edoxaban, in the ASCA region. Moreover, we worked to utilize external resources through alliances and in-licensing while taking steps to incorporate demand in new markets.

As a result, revenue for the ASCA region increased 15.2% year on year, to ¥61.6 billion. Mainstay products such olmesartan, levofloxacin, and pravastatin registered particularly strong sales growth in all countries.

In fiscal 2015, we will target sustainable growth in revenue and operating income in the ASCA region by continuing to pursue maximized sales of existing products and advancing preparation to ensure the quick development and launch of edoxaban and other new products. Expanding operations by utilizing external resources through alliances and in-licensing will also be positioned as a priority measure. We will focus particularly on creating business opportunities through alliances and in-licensing activities with global and local companies in China and Brazil, and we will seek to generate the greatest possible results through these efforts.

The ongoing national campaign to promote vaccinations in Japan has been making headway, which is evident by the country’s verification by the World Health Organization as having eliminated measles in March 2015. Japan has gradually been catching up with the United States and principal European countries in terms of vaccinations, an area where Japan had been lagging behind for some time. Vaccines are growing increasingly more important in Japanese society.

This trend was clearly present in the April 2014 announcement of the Basic Immunization Plan by the Ministry of Health, Labour and Welfare (MHLW), which contained a medium-to-long-term vision for the future of Japan in regard to measures for promoting immunizations.

In April 2015, the Daiichi Sankiyo Group integrated the operating foundations of its vaccine business by transferring all of its vaccine-related functions, with the exception of those related to alliances, to Kitasato Daiichi Sankyo Vaccine Co., Ltd. (KSV). At the same time, we worked to strengthen our integrated scheme for research, development, production, marketing, and sales through organic collaboration with Japan Vaccine Co., Ltd., a joint venture with GlaxoSmithKline K.K., established in 2012 to conduct late-phase clinical development and sales.

The Daiichi Sankiyo Group is committed to contributing to public health by creating innovative vaccines that address social needs and stably supplying high-quality vaccines.

In addition, investigations by the U.S. Food and Drug Administration were smoothly brought to completion during fiscal 2015. DSE is in the process of launching LIXIANA in the European Union under the brand name LIXIANA in June 2015. This grant was awarded for the development of a novel, versatile vaccine candidate, and we are advancing an R&D project with the aim of bringing this candidate to practical application.

Daiichi Sankyo is strengthening its pharmaceutical technology structures while constructing a new manufacturing building equipped with state-of-the-art facilities as part of steps to improve energy efficiency and manufacturing efficiency. At the same time, this company is implementing other various initiatives, including improvement measures aimed at ensuring conformity with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) and GMP standards for pharmaceutical and peripheral manufacturing and quality management as well as guaranteeing stable supply.

The Daiichi Sankiyo Group has been participating in a project on the development / establishment of a production system for new influenza vaccines spearheaded by the MHLW and obtained manufacturing and marketing approval for a cell-cultured HDN1 influenza vaccine in March 2014. Although we were unable to construct the production systems initially planned, we continue to improve manufacturing processes with the aim of creating the necessary supply of this vaccine.

6 North America

6 Europe

6 Vaccines

R&D of vaccines needed in Japan

The Daiichi Sankiyo Group actively engages in the research and development of the “high-priority vaccines” described in the basic immunization plan issued by the MHLW. In 2014, the Company received manufacturing and marketing approval for a 4-valent combination vaccine for the prevention of pertussis, diphtheria, tetanus, and poliomyelitis (polio). We are presently in the process of developing a 5-valent combination vaccine that will protect against infectious disease caused by Haemophilus influenza type b. Another vaccine under development is the MMR combina- tion vaccine, which combines a vaccine for mumps with the measles-rubella combined vaccine (MR vaccine) we are currently marketing. Furthermore, in April 2014, we applied for manufacturing and marketing approval for an intradermal seasonal influenza vaccine in Japan. This state-of-the-art intradermal vaccination product supplies the Company’s influenza HA vaccine profile in an intradermal injection device developed by Terumo Corporation.

In addition to the above, Daiichi Sankiyo was selected for a grant under the Next generation Technology transfer Program conducted by the Japan Science and Technology Agency. This grant was awarded for the development of a novel, versatile vaccine candidate, and we are advancing an R&D project with the aim of bringing this candidate to practical application.

Enhancement of manufacturing and pharmaceutical technology structures and improvement of manufacturing efficiency

KDSIV is strengthening its pharmaceutical technology structures while constructing a new manufacturing building equipped with state-of-the-art facilities as part of steps to improve energy efficiency and manufacturing efficiency. At the same time, this company is implementing other various initiatives, including improvement measures aimed at ensuring conformity with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) and GMP standards for pharmaceutical and peripheral manufacturing and quality management as well as guaranteeing stable supply.

Contribution to national pandemic response project

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Asia, South & Central America

6 Asia, South & Central America

Marketing & Sales
Regarding the operating environment for generic drugs in Japan, accelerated measures to promote the usage of generic drugs are expected to continue growing in fiscal 2015. Accordingly, we will push forward with the expansion of our lineup of premium generic drugs, which are based on the principle of making these drugs safer, more consuming pharmaceuticals, an issue that has recently grown

In fiscal 2014, Daiichi Sankyo Healthcare Co., Ltd. (DSHC) has made every effort to invigorate the market by redoubling the provision of information as well as through in-store promotion activities for growing product categories as well as advancing consumer-oriented development and marketing activities. However, its overall revenue fell 0.5%, to ¥47.8 billion. Noteworthy products include the MINON Skin / Hair washing series of low-instant washing products; the MINON Amino Moist series of low-instant skincare products; the PRECOL Time Release Capsules, a comprehensive cold remedy designed to grant sufficient effects with only two doses per day; and AG Nose Allercut and AG Eyes Allercut, both allergy-agents. Of these products, the MINON Skin / Hair washing series made a particularly large contribution to total sales as a result of the strong benefits of the television commercials and other advertising activities that accompanied its first major brand renewal campaign in 12 years. Conversely, LOXONIN S, an analgesic and anti-inflammatory drug, suffered from fierce competition in its fifth year on the market. As a result, the even-increasing sales that LOXONIN S has recorded since its launch have begun to decline.

Goals and key initiatives in fiscal 2015

In the OTC market, consumers have been increasingly practicing self-care and self-medication as part of their efforts to prevent diseases, to improve their health, and to extend their lifespans. As a result, consumers are becoming more consciousness of their own health. Daiichi Sankyo Healthcare aims to address this trend by focusing on developing products that respond to the diverse needs of consumers who are seeking to be healthier or more beautiful. In particular, we will accelerate the development of switch-OTC products that utilize the know-how of the ethical drug business we possess as an OTC company and step up the activities aimed at providing information related to LOXONIN S and other category 1 OTC drugs. At the same time, we will create new markets by acquiring rights to new materials and active ingredients and developing new products based on fresh ideas. We will also expand sales and improve our income structure by conducting selection and concentration focused on growing markets and enhancing brands.

OTC Business

Initiatives and results in fiscal 2014

In fiscal 2014, the over-the-counter (OTC) drug market benefited from strong sales of products for rhinitis and eye drops stemming from higher levels of pollen dispersion than in the previous year. However, overall OTC drug sales were lower than fiscal 2013 due to poor sales of cold remedies, which represent a significant portion of the market, and the heavy impacts of the rebound from the consumption tax hike in April 2014. Demand rushes were evident during the year for high-priced items such as hair tonics, multivitamins, and revitalizers.

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Initiatives and results in fiscal 2014

In fiscal 2014, the over-the-counter (OTC) drug market benefited from strong sales of products for rhinitis and eye drops stemming from higher levels of pollen dispersion than in the previous year. However, overall OTC drug sales were lower than fiscal 2013 due to poor sales of cold remedies, which represent a significant portion of the market, and the heavy impacts of the rebound from the consumption tax hike in April 2014. Demand rushes were evident during the year for high-priced items such as hair tonics, multivitamins, and revitalizers.

In this environment, Daiichi Sankyo Healthcare Co., Ltd. (DSHC) has made every effort to invigorate the market by redoubling the provision of information as well as through in-store promotion activities for growing product categories as well as advancing consumer-oriented development and marketing activities. However, its overall revenue fell 0.5%, to ¥47.8 billion. Noteworthy products include the MINON Skin / Hair washing series of low-instant washing products; the MINON Amino Moist series of low-instant skincare products; the PRECOL Time Release Capsules, a comprehensive cold remedy designed to grant sufficient effects with only two doses per day; and AG Nose Allercut and AG Eyes Allercut, both allergy-agents. Of these products, the MINON Skin / Hair washing series made a particularly large contribution to total sales as a result of the strong benefits of the television commercials and other advertising activities that accompanied its first major brand renewal campaign in 12 years. Conversely, LOXONIN S, an analgesic and anti-inflammatory drug, suffered from fierce competition in its fifth year on the market. As a result, the even-increasing sales that LOXONIN S has recorded since its launch have begun to decline.

Goals and key initiatives in fiscal 2015

In the OTC market, consumers have been increasingly practicing self-care and self-medication as part of their efforts to prevent diseases, to improve their health, and to extend their lifespans. As a result, consumers are becoming more consciousness of their own health. Daiichi Sankyo Healthcare aims to address this trend by focusing on developing products that respond to the diverse needs of consumers who are seeking to be healthier or more beautiful. In particular, we will accelerate the development of switch-OTC products that utilize the know-how of the ethical drug business we possess as an OTC company and step up the activities aimed at providing information related to LOXONIN S and other category 1 OTC drugs. At the same time, we will create new markets by acquiring rights to new materials and active ingredients and developing new products based on fresh ideas. We will also expand sales and improve our income structure by conducting selection and concentration focused on growing markets and enhancing brands.

When advertising OTC drugs, we not only adhere to related laws, such as the Pharmaceutical and Medical Device Act, the Standard for Adequate Advertisement of Pharmaceutical Products, and the Act against Unjustifiable Premiums and Misleading Representations, but also examine advertisement plans and evaluations at meetings of the Board of Reviewing Promotional Goods and Advertisement of DSHC in accordance with the Guideline for Proper Advertisement, which was instituted by the Japan Federation of Self-Medications Industries.

Voice

Dedication to providing trusted and beloved products

I am positioned in the Skin Care Sales Group. In this group, we work to expand our skincare business by visiting shops and headquarters of drugstore companies together with MIMS to provide information on products and sales promotions. I am primarily responsible for approaching drugstores located in the eastern part of Japan. When going about my job, I focus most on earning the trust of customers. Always valuing communication, I strive to build trusting relationships with customers by addressing their needs in a sincere manner.

One of the products I am responsible for is MINON, a long-selling brand of low-instant washing products designed to be used by customers suffering from sensitive or dry skin and even by babies. Over the 40 years since its launch, this series of products has continued to win the support of customers of all ages. In August 2015, we launched the new MINON product line of medicated haircare products, including MINON Medicated Shampoo and MINON Medicated Conditioner. These products retain their low-instant characteristics while featuring improved tactile sensation. Handling products that were developed by a pharmaceutical company means that it is my duty to provide customers with the type of easy-to-understand information steeped in insight and scientific evidence that we are able to offer as a pharmaceutical company. My own skin has been quite sensitive since I was a child, and I have been using low-instant...